



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

WOLLMER ET AL.

Atty. Ref.: 613-101; Confirmation No. 1945

Appl. No. 10/563,828

TC/A.U. 1618

Filed: May 8, 2006

Examiner: Samala

For: MICROEMULSIONS AND ITS USE FOR PREVENTING AIRWAY DISEASES

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

EVIDENTIARY DECLARATION UNDER 37 CFR §1.132

I, Tomas Landh, one of the joint inventors in the above-identified application, do hereby declare:

1. That my residence and citizenship are of record in this application as stated in my declaration as inventor made under 37 C.F.R. §1.63 and that I am employed by Novo Nordisk A/S, Denmark.
2. That I am familiar with the contents of the above-identified application and the research effort underlying this application.
3. That I have read and am familiar with the Office Action of 28 April 2009 and with the contents of US 6506803 and US 6618840.
4. That according to traditional emulsion technology an "emulsion" is formed of discrete droplets dispersed and kinetically stabilised in a continuous phase. In an "oil in water" emulsion, stabilised droplets are dispersed in an aqueous environment.

5. That traditional oil in water emulsions are cloudy in appearance and are discontinuous with respect to the oil phase i.e. it does have a continuous structure and are thermodynamically unstable.

6. That in contrast, to "emulsions", "microemulsions", such as the microemulsions of the present invention, are based on mixtures of polar and non-polar lipids which typically form transparent, thermodynamically stable more or less structured phases.

7. That the phase structures available to pure lipids depend upon their chemical structure and resultant intrinsic properties, such as spontaneous curvature.

8. That the phase structures available to a mixture of amphiphilic components depends upon the properties of the individual components, upon their ratios and upon their interactions. Thus a component with negative curvature may be present in a mixture exhibiting positive curvature as a whole.

9. That the phase structure of a microemulsion is a property of the composition as a whole and is dependent upon many factors including the amount of each component having positive or negative spontaneous curvature, the degree of that curvature in each case, and the interactions of the components..

10. That I have studied compositions of the type recited in the claims of the above-identified application and have observed their properties and phase behaviour.

11. That I have observed the need for at least a minimum amount of glycerol monooleate in compositions of the type claimed in the above-identified application in order to form reversed phase microemulsions.

12. That based upon my practical experience of microemulsions I believe that it is necessary to have at least around 20 % glycerol monooleate in order to form the reversed phase microemulsions of the type recited in the claims of the above-identified application.

13. That based upon my practical experience of working with microemulsions, I believe that the combinations of components indicated in US 5618840 and US 6596803 would lead to the formation of traditional emulsions rather than reversed phase microemulsions

I declare further that all statements made herein of my/our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 26 October 2009



Tomas Landh